

# Randomised trial of reamed versus non-reamed nails in tibial fractures

**Submission date**  
29/06/2004

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☒ Protocol

**Registration date**  
22/07/2004

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
30/01/2019

**Condition category**  
Injury, Occupational Diseases, Poisoning

☐ Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://www.sprint-trial.com/index.shtml>

## Contact information

### Type(s)

Scientific

### Contact name

Dr Mohit Bhandari

### Contact details

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**  
NCT00038129

## **Secondary identifying numbers**

MCT-38140

# **Study information**

## **Scientific Title**

Randomised trial of reamed versus non-reamed nails in tibial fractures

## **Acronym**

SPRINT

## **Study objectives**

Our primary objective is to assess the impact of reamed versus non-reamed intramedullary nailing on rates of re-operation (including bone grafts, operation for infection, dynamisation; removal of locking screw(s) due to hardware breakage or loosening of screws, and fasciotomy for intra-operative or post-operative compartment syndrome) in patients with 50% or greater cortical continuity, or less than 1 cm gap between the fracture ends post intramedullary nailing.

Our secondary objective is to assess the impact of reamed and non-reamed intramedullary nailing on functional status, quality of life, and return to normal activities.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Ethics approval received from the Research Ethics Board of McMaster University, Hamilton, Ontario (Canada) on the 20th April 1999 (ref: # 99-077).

## **Study design**

Multicentre, international, two arm, randomised parallel surgical trial with data analyst blinded.

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Treatment

## **Participant information sheet**

## **Health condition(s) or problem(s) studied**

Tibial shaft fractures

## **Interventions**

### Reamed Nail Insertion:

Reaming is conducted over the guide wire with cannulated power reamers. The attending surgeon chooses the reamer. To avoid inconsistencies in the degree of reaming, surgeons adhere to the following protocol:

1. Surgeons ream the intramedullary canal until the first detection of "cortical chatter" (i.e. the reamer just begins to contact the cortical bone of the tibia)
2. The size of the nail (diameter) corresponds to the point of "cortical chatter" (if chatter occurs with a 11 mm reamer, then the nail size is 11 mm)
3. Following the appearance of "cortical chatter" surgeons ream 1 - 1.5 mm larger than the chosen nails diameter to facilitate its insertion

The chosen nail, which is as long as possible without distracting the fracture by impinging on dense distal metaphyseal bone or protruding above the cortex at the insertion site, is inserted with the appropriate instruments. Distraction of a tibial shaft fracture interferes with healing, so surgeons employ all strategies for achieving cortical contact (up to 10 mm shortening acceptable to achieve contact of fracture ends). The choice of intramedullary nail manufacturer and material (titanium or stainless steel) is at the discretion of the operating surgeon.

### Non-Reamed Nail Insertion:

Surgeons insert non-reamed nails across the fracture site ensuring minimal distraction. The goal is to achieve cortical contact of the fracture ends. An upper diameter limit of 10 mm is employed for non-reamed nails. However, in principle the nail should be at least 2 mm less than the diameter at the isthmus of the tibia on anteroposterior and lateral radiographs.

For further information, please contact Dr Bhandari at the address listed below or the principal investigator Dr Gordon Guyatt.

### Intervention Type

Other

### Phase

Not Specified

### Primary outcome measure

Impact of reamed and nonreamed intramedullary nailing on:

1. Rates of re-operation
2. Rates of complications

### Secondary outcome measures

Functional status using:

1. The Health Utilities Index
2. 36-item Short-Form health survey
3. Tibia Knee Pain Questionnaire
4. The Short Musculoskeletal Functional Assessment

### Overall study start date

01/01/2000

### Completion date

30/03/2007

# Eligibility

## Key inclusion criteria

1. 900 patients of either sex
2. Aged 18 and over
3. With a sustained tibial fracture that requires an operative treatment
4. In 10 Canadian and 13 US centres

## Participant type(s)

Patient

## Age group

Adult

## Lower age limit

18 Years

## Sex

Both

## Target number of participants

900

## Key exclusion criteria

1. Fractures not amenable to intramedullary nailing (less than 5 cm distal to the tibial tubercle, or less than 5 cm proximal to the tibiotalar joint)
2. Inability to pass a non-reamed nail
3. Fractures with associated neurovascular deficits (Gustillo Grade IIIC injuries)
4. Pathologic fractures
5. Surgical delay of greater than 12 hours from time of injury (open fractures)
6. Surgical delay of greater than 3 weeks from time of injury (closed fractures)
7. Retained hardware in the affected limb that would interfere with intramedullary nailing
8. Associated fractures of the foot, ankle, or knee
9. Likely problems, in the judgment of the investigators, with maintaining follow-up. For example, we will exclude patients with no fixed address, those who report a plan to move out of town in the next year, or intellectually challenged patients without adequate family support

## Date of first enrolment

01/01/2000

## Date of final enrolment

30/03/2007

# Locations

## Countries of recruitment

Canada

United States of America

**Study participating centre**  
**McMaster University**  
Hamilton, ON  
Canada  
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## Sponsor information

**Organisation**  
McMaster University (Canada)

**Sponsor details**  
Office of the Associate Dean Research  
Faculty of Health Sciences  
1200 Main St. West, room HSC-3N8  
Hamilton  
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hsresadm@mcmaster.ca

**Sponsor type**  
University/education

**Website**  
<http://www.mcmaster.ca/>

**ROR**  
<https://ror.org/02fa3aq29>

## Funder(s)

**Funder type**  
Research organisation

**Funder Name**  
Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-38140)

## Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	23/06/2008	30/01/2019	Yes	No
<a href="#">Results article</a>	results	01/06/2012	30/01/2019	Yes	No
<a href="#">Results article</a>	results	01/11/2009	30/01/2019	Yes	No
<a href="#">Results article</a>	results	01/06/2011	30/01/2019	Yes	No
<a href="#">Results article</a>	results	01/09/2016	30/01/2019	Yes	No